

# SEABOARD farms

March 31, 1999

4704 '99 APR -7 12:10

Dr. Margaret Miller  
HFV-1, Room 482  
FDA, Center for Veterinary Medicine  
7500 Standish Place  
Rockville, MD 20855

Dr. Miller,

As a poultry industry veterinarian representing one of the top ten broiler producing companies in this country, I am writing to express my concern regarding the document titled "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals." My concerns stem from the potential for this proposed document to virtually eliminate the discovery and development projects many of the pharmaceutical companies have ongoing that would ultimately benefit the food animal industry and, ultimately, the consumer. Additionally, the way this proposal reads, there are no provisions for modification of drug use within food animal medicine. The only action appears to be removal of drugs from the market. While my concerns regarding the limitation of new drugs to the industry and the loss of currently approved drugs are great, an even greater concern is that while accomplishing this, we will be no further along in identifying causes of the real problem at hand – increasing bacterial drug resistance within the human population.

While I don't dispute that bacterial exposure to antimicrobials in food-producing animals may play some role in the current problem, I think we must examine the judicious use of these compounds in their entirety – in companion animals and most certainly in humans. I would like to see a more unified approach to attacking this problem where each group is held accountable for their part and that, as a group, we can agree on the best ways to monitor, detect, and act on a change in bacterial resistance patterns within a population. I would hope that before any legislation was adopted that your agency and the AVMA along with other interested parties (Association of Veterinarians in Broiler Production, Association of Veterinarians in Turkey Production, American Association of Avian Pathologists as examples of poultry groups) could

98D-1146

C26

reach agreement on the best way to accomplish the primary goal which I believe is a reduction in the development of bacterial resistance in the human population. I am aware that some of this dialogue has already occurred and from what I can glean there is still a division on which approach to take to address this issue.

No one would put more importance on an animal life than a human life. We need antimicrobials that are, and will continue to be, efficacious in the human population. As a veterinarian, I also need "tools" to help maintain the health of those that I have been entrusted to care for. The poultry industry places great importance on disease prevention through vaccination programs and best management practices developed to minimize stress and disease challenge while maximizing performance. There are times, however, when animals do get sick and antimicrobials are needed. With decreased availability of efficacious compounds, there will certainly be an adverse economic impact on the food animal industry and the consumer but, more importantly, I believe it will negatively impact animal suffering and, ultimately, the wholesomeness of animal products.

In conclusion, I would like to support your group working as a team with other interested parties to address the concerns the industry shares with the FDA. These include addressing 1) the problem of emerging bacterial drug resistance through a well-thought-out scientifically-based action plan that continues to allow the food animal veterinarian the latitude to make judicious choices from a list of efficacious compounds, 2) the judicious use of antimicrobials within other groups that have use of these drugs within their domain, and 3) the development of scientifically-based post-approval monitoring programs that will aid in the determination of increasing resistance in bacterial populations.

Thank you for your time and attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kenneth Opengart', with a large, stylized loop at the end.

Kenneth Opengart, DVM, PhD, Diplomate ACPV  
Director of Veterinary Services